UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

-v-

MERUS N.V.,

Defendant.

14-cv-1650 (KBF)

OPINION & ORDER

KATHERINE B. FORREST, District Judge:

On March 11, 2014, this case began as a suit for patent infringement. After this Court issued its claim construction opinion on November 21, 2014, Regeneron Pharmaceuticals, Inc. stipulated that its infringement claim must fail if the Court's constructions withstood challenge on appeal. Soon afterward, all that remained was Merus's counterclaim against Regeneron for inequitable conduct during patent prosecution. On June 9-15, 2015, this Court held a bench trial on that claim. The resulting Opinion, issued on August 6, 2015, not only held that Regeneron's patent was invalid for inequitable conduct but also sanctioned Regeneron for misconduct throughout the litigation. (ECF No. 411.) The Federal Circuit affirmed this Court on July 27, 2017 and denied Regeneron's petition for rehearing en banc on December 26, 2017.

Now pending before the Court is defendant Merus's motion for attorney fees. (ECF No. 425.) This motion was originally made on November 16, 2015, but the

Court stayed it pending appeal. (ECF No. 431.) The stay was lifted on January 18, 2018, (ECF No. 455), and the motion became fully briefed on March 12, 2018, (ECF Nos. 426, 466, 467).

For the reasons set forth below, Merus's motion for attorney fees is GRANTED.[1]

I. BACKGROUND

In describing the background and history of this case, the Court relies largely on its previous Opinion holding, inter alia, that Regeneron engaged in inequitable conduct during patent prosecution. Regeneron Pharm., Inc. v. Merus B.V. ("Regeneron I"), 144 F. Supp. 3d 530, 536 (S.D.N.Y. 2015).

On March 11, 2014, Regeneron filed twin patent infringement actions: one against Merus B.V.[2] ("Merus"), a company based in the Netherlands, and another against Ablexis LLC ("Ablexis"). In short complaints, each consisting of a few substantive paragraphs, Regeneron accused both companies of infringing U.S. Patent No. 8,502,018 ("'018 Patent"). Merus answered and counterclaimed, arguing that the '018 Patent was unenforceable due to Regeneron's conduct during patent prosecution. Following issuance of this Court's opinion on claim construction, Regeneron stipulated that its infringement claim as to Merus must fail if the Court's constructions withstand challenge on appeal. Thereafter, Ablexis settled with Regeneron prior to claim construction; all that remained was Merus's

[1] At issue now is solely the question of whether Merus will be awarded attorney fees; while Merus's motion is granted, the specific amount has yet to be briefed and determined.

[2] In Mary 2016, Merus changed its name from Merus B.V. to Merus N.V.; on January 18, 2018, the Court granted Merus's motion to amend the case caption accordingly. (ECF No. 456.)

counterclaim for inequitable conduct. On June 9-15, 2015, this Court held a bench trial on that claim.

Noting that the litigation should never have commenced, this Court found that Regeneron engaged in inequitable conduct both during patent prosecution and continued its misconduct throughout litigation. "Troubling litigation tactics were on display soon after this case was filed and continued into the trial." Regeneron I, 144 F. Supp. 2d at 537.

A. Conduct During Patent Prosecution

U.S. Patent Application No. 13/164,176 (the '176 Application), entitled "Method of Modifying Eukaryotic Cells," was filed on June 20, 2011. The application issued as U.S. Patent No. 8,502,018 (the '018 Patent) on August 6, 2013, to inventors Drs. Andrew J. Murphy and George D. Yancopoulos, and was assigned to Regeneron. The patent "relates to using large DNA vectors to target and modify endogenous genes and chromosomal loci in eukaryotic cells. One practical use of this technology is that users may target and modify specific genes in mice so that the mice develop antibodies that can be used by humans." Regeneron Pharm., Inc. v. Merus N.V. ("Regeneron II"), 864 F.3d 1343, 1347 (Fed. Cir. 2017) (internal citation omitted).

As originally filed, claim 1 of the '176 Application describes a genetically modified mouse, comprising in its germline human unrearranged variable gene region segments inserted at a mouse immunoglobulin locus. (DX 2 at 44.) But for

the later inclusion of the word "endogenous," this is identical to claim 1 of the '018 Patent as issued.

On January 26, 2012, the PTO issued a Non–Final Office Action rejecting claims 1-19 of the '176 Application as being anticipated by a Lonberg reference, 2006/0015957 (Id. at 128-39.) That Office Action stated, in part:

> Lonberg and Kay teach heterologous unrearranged immunoglobulin human heavy and light chain transgenes useful for producing transgenic mice . . . and transgenes are typically integrated into host chromosomal DNA, into germline DNA.
> . . .
> Lonberg and Kay teach the production of chimeric human variable region/mouse constant region antibodies through trans-switching . . . thus the mouse does not comprise a human immunoglobulin constant region gene.

(Id. at 131-32.) On July 26, 2012, Regeneron's Dr. Tor Smeland, in-house counsel responsible for prosecuting that application and others in the same family in the United States and Europe, replied to this Office Action. He argued, inter alia, that unlike the '176 Application, Lonberg teaches random and not targeted insertion:

> Lonberg does not disclose a mouse comprising in its germline human unrearranged variable region gene segments inserted at a mouse immunoglobulin locus. Instead, Lonberg discloses transgenes that are apparently randomly inserted at (unknown) loci. Lonberg simply lacks description of the claimed chimeric locus of claim 1. Amended claim 11 and amended claim 20 also recite a chimeric endogenous locus, which is not disclosed in Lonberg. Thus, regardless of whether Lonberg disclosed chimeric human variable/mouse constant antibody proteins, Lonberg does not anticipate the claims because a disclosure of trans-switching does not disclose . . . endogenous mouse loci that are modified as claimed . . . .
>
> . . .
>
> The claimed method does not represent a selection from predictable solutions, i.e., the claimed method was not "obvious to try" at the time

> it was filed. An obvious to try argument assumes a design need or market pressure to solve a recognized problem in order to achieve an anticipated success. The art never recognized (1) that there was a "problem" to be solved in making antibodies from an endogenous mouse locus, or (2) that there was a design need or market pressure to achieve success at modifying an endogenous mouse immunoglobulin locus to make a chimeric endogenous locus.

(Id. at 160-61, 163 (emphasis added).) On October 11, 2012, the PTO mailed a Final Office Action, rejecting the pending claims of the '176 Application. The Final Office Action maintained the rejection of claims 1-19 as anticipated by Lonberg. (Id. at 180.)

In a January 11, 2013 Reply to the Final Office Action, Regeneron amended claim 1 to include the additional limitation that the human unrearranged variable region gene segments would be inserted at "an endogenous" mouse immunoglobulin locus. (Id. at 202.) In connection with that amendment Regeneron stated:

> The Lonberg paragraphs cited by the Examiner merely disclose that human transgenes for making human antibodies were mentioned in the art. None of the cited paragraphs suggest or even hint at placing unrearranged human immunoglobulin gene segments at an endogenous mouse locus, much less a functional endogenous mouse locus. The cited portions of Lonberg leave no doubt whatsoever that the Lonberg mouse construction instructions were to build a transgenic mouse that makes fully human antibodies from transgenes that are distant from endogenous mouse immunoglobulin loci; i.e., they are synthetic loci randomly inserted into the mouse genome at a locus distant from any functional mouse immunoglobulin locus. Indeed, as is described in detail elsewhere in Lonberg, the Lonberg transgenic mouse requires that endogenous mouse immunoglobulin loci (both heavy and light chain loci) must be rendered non-functional so as to allow the fully human immunoglobulin transgenes to make fully human antibodies. There is absolutely no hint or suggestion in Lonberg to employ a functional endogenous mouse locus having inserted unrearranged human immunoglobulin variable region gene segments in the functional locus.

(Id. at 204–05.) The reply also represented that the VelocImmune mouse is the commercial embodiment of the invention:

> However, regardless of whether the Examiner has made a prima facie case of obviousness with respect to claim 20, Applicants submit that claim 20 is patentable because the claimed mouse exhibits features entirely unexpected in lights of the teachings of prior art (e.g., Lonberg, Brüggemann, Kawasaki, and Popov). The features of mice having disabled endogenous immunoglobulin loci and comprise transgenes that make antibodies with human variable domains have been disclosed in peer-reviewed publications disclosed in the information disclosure statement filed in this application, dated 20 September 2011. The claimed mice, an embodiment of which is known in the art as a VELOCIMMUNE humanized mouse, perform surprisingly and unexpectedly better than mice with disabled endogenous loci that express antibodies from randomly inserted transgenes (as in all of the references cited by the Examiner).

(Id. at 209 (emphasis added).)

Attached to Regeneron's reply was a slide presentation, (id. at 214-32), that Dr. Smeland provided to the PTO, and which he and Brendan Jones, an outside patent attorney retained to represent Regeneron in the final stages of prosecution of the Patent, relied on in a meeting with the PTO. (See id. at 290.) That presentation contains information which Merus asserted is false and was known to be false at the time. It concerns the VelocImmune mouse to which Dr. Smeland's January 2013 reply referred. Various figures in that presentation describe ways in which the VelocImmune mouse was made. These figures are consistent with the presentation's assertion that the VelocImmune mouse was "[c]reated only by virtue of VelociGene & VelociMouse technologies." (Id. at 215.)

This Court ultimately agreed with Merus that these slides provide certain misleading and inaccurate information. See Regeneron I, 144 F. Supp. 3d 350.

First, as of February 2001, the VelocImmune mouse did not exist—Regeneron had been unable to make it. (See, e.g., DX 14520; REGN-AM-10055694.) Yet the presentation suggested that it did. In addition, on slide 10, a figure depicts the locus construction for the VelocImmune mouse and indicates that Regeneron replaced a 3 mb segment with a 150 kb segment in a single step; that is, that both insertion and deletion occurred simultaneously. (DX 2 at 224.) This was not in fact the process used to produce the VelocImmune mouse. (Davis Tr. Decl. ¶ 279.) Insertion of both human heavy and light chain variable regions requires two steps (or a breeding step), and a third step is required to delete or inactivate the homologous mouse sequence in order to obtain therapeutically useful antibodies. Regeneron I, 144 F. Supp. 3d at 556.

Moreover, in February 2001 (and for a substantial number of years thereafter), Regeneron had not succeeded in inserting and deleting a portion of mouse IgH DNA that was over 200 kb. (See, e.g., DX 145; REGN-AM-10055694.) Nevertheless, the '018 Patent depicts this in Figure 4 and the presentation indicates that insertion and deletion on this scale had occurred. Figure 4 of the '018 Patent shows a replacement of approximately 200-300 kb of human immunoglobulin DNA for mouse immunoglobulin DNA. ('018 Patent at fig. 4.)

In addition, the presentation discusses the ability of the VelocImmune mouse to preserve the transmembrane and cytoplasmic DNA of the endogenous mouse immunoglobulin locus as among its benefits over prior art mice. (DX 2 at 219, 222.) The presentation discusses the preservation of these regions as the "VelocImmune

Hypothesis." (Id. at 226.) But neither the claims nor the specification contains such a limitation. (See '018 Patent, 3:27-8:3, 29:24-30:64.) Moreover, this concept was not novel. One of the references Regeneron had not disclosed to the PTO, Zou, in 1994 disclosed the preservation of mouse constant cytoplasmic and transmembrane domains and stated that the mice produced humanized antibodies "at the same level and efficiency as wild-type mice produce murine IgG1 antibodies." (DX 72, Zou, et al. (1994) at 1099.) These undisclosed results undercut the claims of the VelocImmune mouse's superiority found in Dr. Smeland's January 2013 presentation, which extolled "[n]ormal variable region usage and junctional diversity," as well as "[n]ormal numbers and distribution of B cells in spleen and lymph node" and "[n]ormal B cell differentiation in bone marrow." (DX 2 at 227; Davis Tr. Decl. ¶ 349.)

Dr. Andrew Murphy of Regeneron was one of the authors (but not presenters) of the slides that were provided to the PTO during patent prosecution. Prior to creating the January 2013 slide deck, Dr. Murphy had been told by another pioneering scientist in the field who had been on Regeneron's Scientific Advisory Board, Dr. Frederick W. Alt, that assertions that VelocImmune mice demonstrated no major defects in B cell differentiation "could be a little misleading." (DX 223 at 10039849; DX 111 REGN–AM–00061940.) Dr. Alt shared this comment in an August 15, 2011 message that provided comments on a manuscript Dr. Murphy had sent Dr. Alt and others the prior March. In the March email, which was titled "VelocImmune manuscripts," Dr. Murphy had told the recipients they were "listed

as a co-author in one or both of the enclosed manuscripts," and asked for any edits. (DX 112.)

In his comments on August 15, 2011, Dr. Alt responded to an assertion in the manuscript that read: "No major defects were observed in B cell differentiation in any of the VelocImmune mice. The introduction of human IgH variable segments does not appear to affect either the pro B to pre-B transition nor do human IgK variables affect the proB to B transition." (DX 223 at 10039848.) Dr. Alt wrote that, in his view, this statement was "correct but perhaps could be a little misleading." (Id. at 10039849.) He explained:

> when we looked at bone marrow BM there was a profound block in the pro-B and pre-B transition, suggesting that there is significant selection/expansion of the 3 human VH locus to get a normal percentage of B cells in the periphery . . . . [I]n reality if you have too few human VH then you may have impaired development and therefore the number of VHs is important, but once you have a certain number of VH genes (for example 18 in Velcoimmune), there is no obvious developmental impairment."

(Id.)

Another recipient of that same email, Dr. Klaus Rajewsky also provided comments to Dr. Murphy. He advised Dr. Murphy that "[s]ince the first paper deals in depth with the issue of replacing mouse by human immunoglobulin gene segments, it may be appropriate to quote the first paper(s) demonstrating such replacements, which were actually done in my lab almost 20 years ago. The references are attached." (DX 113.) One of the attached references was the Zou reference that is alleged to be one of the Withheld References in this proceeding.

Having received this information from both Drs. Alt and Rajewsky, and without any evidence in the record suggesting his colleagues' comments were unfounded or incorrect, Dr. Murphy nevertheless assisted in authoring the presentation to the PTO that continued to assert that the VelocImmune mouse with 3 VH gene segments was "normal" meaning "identical to wild-type mouse littermates," ignoring Dr. Rajewsky's prior lab work and the Zou publications. (DX 2 at 227.)

Following receipt of the January 2013 presentation from Dr. Smeland, the PTO issued an Advisory Action maintaining the rejection of claims 1-19 as anticipated by Lonberg, and claim 20 remained rejected in view of Lonberg and other references. (Id. at 241, 248.) Shortly thereafter, on February 19, 2013, Regeneron retained Brendan Jones, Ph.D., to assist with prosecution. (Id. at 268.) Drs. Jones and Smeland together planned an in-person meeting with the PTO at which Regeneron relied on the previously provided slide deck described above. That meeting occurred on March 11, 2013, exactly one year before this lawsuit was filed. (Id. at 290.)

Following that meeting, the Examiner prepared the following notes: "Applicant's representatives discussed that Lonberg does not teach integration of human unrearranged immunoglobulin genes into an endogenous site of a mouse immunoglobulin locus as required by the instant claims." (Id.) The Examiner agreed to review the pending application. (Id. at 301.)

On April 26, 2013, the PTO issued a Notice of Allowance for the '176 Application. (Id. at 285.) In the statement of reasons for allowance, the Examiner stated that "[t]he prior art does not teach or suggest a genetically modified mouse comprising, in its germline cells, human unrearranged variable region gene segments inserted at an endogenous mouse immunoglobulin locus." (Id. at 283; ECF No. 241 ¶ 172.) The applicant transmitted the fee on June 28, 2013 and the patent issued as the '018 Patent on August 6, 2013. (DX 2 at 328-29, 339; '018 Patent.)

This Court found that during patent prosecution for the '018 Patent, Regeneron failed to disclose but-for material information to the PTO, violating its duty of candor and disclosure. Regeneron I, 144 F. Supp. 3d at 562. Specifically, Drs. Smeland and Murphy did not disclose four known references (the "Withheld References"). The Court went through each of the Withheld References and determined that each would have formed the basis for the PTO to reject Regeneron's patent applications. Id. at 571-75.

Ultimately, the Court agreed with Merus that "Regeneron committed affirmative egregious misconduct in connection with prosecution of the '018 Patent" through its "(1) statements in the specification disproven by Regeneron's own subsequent patent applications; (2) the specification making inaccurate or incomplete statements with regard to the use of LTVECs; and (3) a presentation to the PTO which contained statements that Regeneron knew at the time to be false." Id. at 582 (internal citations omitted). This finding was supported by clear and

convincing evidence, and without the need for application of an adverse reference. Id. at 585. Accordingly, the Court found "by clear and convincing evidence that this constitutes egregious affirmative misconduct." Id.

B. Regeneron's Litigation Conduct

Regeneron's misconduct did not cease after the patent was awarded. Regeneron filed a lawsuit against Merus for infringement and continued its shenanigans throughout discovery and, indeed, up to the eve of trial.

Early on, when the Court's Individual Patent Rules required Regeneron to disclose to Merus its infringement contentions, broken down by element, (see Indiv. Patent Rules 1(a)(iii)), Regeneron claimed that it could not comply. Instead, Regeneron provided a chart with infringement contentions that listed each claim as consisting of a single limitation—that is, a single element. Merus moved to compel—seeking real infringement contentions. (See ECF No. 76.) In that same motion, Merus also moved to compel production of documents as required by the Court's rules relating to the conception and reduction to practice of the '018 Patent. Regeneron claimed to have very few such documents and did not include in its production a key document written by Dr. Murphy, one of the inventors, setting forth the '018 Patent's conception and reduction to practice. (DX 145.)

The Court issued a written decision in response to Merus's motion to compel Regeneron to detail its infringement contention. (ECF No. 82.) At a subsequent conference, the Court discussed its concerns with Regeneron's conduct and gave Regeneron an opportunity to correct it. In both its Order and at that conference,

the Court noted that the infringement claim that Regeneron had asserted—as with all infringement claims—required an element-by-element identity between the accused product and the '018 Patent. See Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1296 (Fed.Cir. 2009). The Court stated explicitly, both in its written decision on this issue and at a hearing held soon thereafter, that it was troubled by Regeneron's refusal. At that time, experienced patent counsel (subsequently replaced by Regeneron's trial counsel) asserted that he did not understand what the Court was asking for or how to break a claim down into elements. This made no sense and was clearly a tactical choice—seeking to shift the plaintiff's burden in an infringement case to define the elements of a claim to the defendant, maintaining maneuvering room as a result. In retrospect, the reasons for this choice became clear: an element-by-element breakdown of the claim would have eliminated the host of additional, non-claim specific limitations that are necessary for Regeneron to prevail.

During claim construction, Regeneron again chose tactics over substance. The Court's rules required that Regeneron, as the plaintiff, propose its claim constructions, then that the defendant respond. (See Indiv. Patent Rule 2(a)(i), 2(c)(i).) Regeneron took the position that no terms required construction. The Court issued an order (ECF No. 81) expressing its concern that Regeneron was attempting to "game" the system by shifting the burden to Merus to propose constructions and then to take shots at those proposals. The Court required Regeneron to live by its plain language constructions. (The short-sightedness of

Regeneron's position became all the more clear in light of the extensive constructions offered by Dr. Oettinger.)

Additionally, Regeneron's conduct relating to what was and is referred to as the "Jones Memo" was also troubling for multiple reasons. First, it followed the pattern of misconduct the Court has already described. Second, Regeneron sought to use it as a cloak for the instances of misconduct that were the primary bases for the Court's sanctions decision: the broad waivers effectuated by the Smeland declaration and the host of discovery issues revealed by the Court's ensuing review of Regeneron's privilege log. When, as discussed below, Regeneron broadly waived the privilege in the Smeland trial affidavit but argued it was justified in nonetheless maintaining its privilege as to numerous documents on the same topics on its privilege log, its confusing defense was that, as it had complied with the Court's waiver Order regarding the Jones Memo (an entirely different issue), it had no obligation to make such disclosure. There was no comprehensible reason provided as to why compliance with an Order on waiver as to one situation could provide any reasonable basis for failure to disclose in another.

The Jones Memo issue developed as follows. Discovery was in process and depositions ongoing. On the eve of Dr. Jones's deposition, Regeneron made a tactical decision to disclose a helpful chart and memorandum Dr. Jones had prepared in connection with his review of whether to disclose the Withheld References during patent prosecution. These materials had previously been listed on Regeneron's privilege log on the basis of attorney-client privilege. Merus

asserted a broad privilege waiver and brought a motion to compel. The evidence presented to the Court on that motion demonstrated that on November 7, 2013, Dr. Jones had attached the chart to an email to Dr. Smeland, and wrote, "While we discussed this analysis in numerous calls, I don't know if I have ever sent you this document. For your records, I have also attached a memo I drafted regarding the third-party disclosures made in the other U.S. case." (ECF No. 223.) That email was forwarded to Regeneron's then-outside counsel on the same day.

On November 11, 2014, Regeneron's outside counsel wrote an email to Regeneron stating, "I believe Brendan also discussed his analysis with Tor around the time that Brendan prepared these memos." That same e-mail notes that Dr. Jones "was asked to analyze]] whether certain references that came up in the European Opposition and the Third Party Submission should be disclosed to the PTO", and that "[t]here are several documents that he prepared on this subject in late June 2013."

In fact, the memorandum, written by Dr. Jones on June 28, 2013, appeared in all respects to be formatted and have the content of a legal memo to Regeneron—though it is designated as a memo to file. Printed on Foley Hoag letterhead and beginning with entry lines for "to," "cc," "from," and "regarding," the memo read "Privileged and Confidential," began with a summary section, contains footnotes, and is organized under formal headings. It described basic standards for the duty to disclose prior art and analyzed the materiality of three publications. The memo amounted to an elucidation of the rationale underlying the charts and is

inextricably connected to the charts. The document was plainly one created in connection with Dr. Jones's provision of legal advice to Regeneron.

The references to discussions of the chart and analysis made clear that Dr. Jones analyzed the prior art and arrived at a legal conclusion regarding a disclosure obligation as part of his advisory role to Regeneron. He contemporaneously communicated the substance of the very same advice to his client. The Court found that Regeneron's argument in opposition to the motion to compel—that the documents were not privileged because Dr. Jones had merely used them to assist himself in connection with some professional obligation unrelated to his advisory role to Regeneron—was "seriously incorrect." (ECF No. 223 at 7.)

As part of its inquiry into this waiver—now called the Jones Memo issue—and particularly for the purpose of understanding what the universe of documents were that would be implicated by such waiver, the Court requested that Regeneron provide it with "[a]ll documents relating to groups or individuals who at the time of creation or subsequently thereto received a copy of the chart or memo" and "[a]ll documents and communications . . . referring or relating in any way to Dr. Jones's chart and memo." (ECF No. 214 (emphasis added).) The Court sought these documents for its in camera review and anticipated that all documents discussing the materiality or cumulativeness of the Withheld References that had been withheld on the basis of privilege would be included in any such production. Regeneron subsequently provided a single binder to the Court containing what it represented constituted the universe of such materials (subject to an explicit

disclosure as to that which it had held back, which related solely to certain specified litigation materials). (ECF No. 223 at n.2.) The Court was thus led to believe that it had before it all of the documents that related "in any way" to Dr. Jones's chart and memo.

As it has turned out, this was not the case. Regeneron had not in fact provided the Court with the entire universe but had sua sponte imposed its own limitation that required any documents be directly related to the chart and memo—not "in any way" related, as the Court's order required. Thus, the Court's intention to include all documents concerning the subject matter was circumscribed—and Regeneron appeared to have included only documents directly and explicitly related to the chart and memo themselves. The Court believed the binder provided insight into all that was at issue; but the Court was in a dark room and mistook the leg of an elephant for a pillar. The Court ruled on the motion.

Because Regeneron affirmatively produced these two documents to Merus prior to a deposition, believing they were helpful, it waived the attorney-client privilege with regards to the same subject matter. The Court found that this presented a classic "sword and a shield" issue. See In re Grand Jury Proceedings, 219 F.3d 175, 182 (2d Cir. 2000); United States v. Bilzerian, 926 F.2d 1285, 1292 (2d Cir. 1991). The Court ordered that "Regeneron and Foley Hoag produce to Merus all relevant documents concerning the decision to not disclose prior art during the patent prosecution." (ECF No. 223 at 9 (internal alteration omitted).)

The Court assumed that this covered the universe and that the universe was thus contained in the binder. Only Regeneron knew what in fact existed.

Unsurprisingly, there was a dispute as to the scope of the waiver. The Court approached the dispute based on its experience on the prior motion and in light of the binder of privileged documents previously provided. Regeneron represented that it had produced:

> all documents and communications related to any decision, analysis or advice by Dr. Jones or anyone at Regeneron on whether or not to disclose references from Dr. Jones' charts and memo during prosecution of the '018 patent. In searching for this information, Regeneron: searched documents from Messrs./Drs. Pobursky, Kang, Gregg, Yang, Smeland, Yancopoulos, Sheasby, Murphy, Stevens, MacDonald, Karow, Valenzuela, and Economides . . . .

(ECF No. 262, Exh. 12.) Regeneron also asserted broadly that it had produced all of its communications or attachments thereto from the time period of the prosecution of the '018 Patent "that even mentioned the content of any of the references cited" in the chart and memo. (ECF No. 261, at 7-8.) Regeneron argued against Merus's request to impose sanction for non-compliance with the Court's order by stating that it had explained to Merus that its production was tailored to the subject matter of the Jones documents. Regeneron also argued that broader disclosure could result in serious prejudice as it could impact a pending appeal it had for EP '287, which was then in the midst of being briefed. (ECF No. 261, at 8.)

At that time, the Court viewed the issue as a good-faith dispute over the scope of the Court's December 5 Order and read Regeneron's representations as statements that any references in any of its privileged documents to the Withheld

References during the appropriate timeframe had been produced. As subject matter waiver seeks to readjust the essential unfairness in disclosing part, but not all, of an attorney-client communication, see In re Claus von Bulow, 828 F.2d 94, 101, 102-03 (2d Cir. 1987), the required remedy should be addressed to that particular unfairness, see In re Grand Jury Proceedings, 219 F.3d at 182.

In terms of scope, and of course based on what the Court believed was the universe of documents at issue, the Court sought to determine what—in fairness—Merus needed to receive to avoid the sword/shield issue. The Court determined that fairness required Regeneron to produce any documents which reflected additional thoughts, concerns, and considerations given to whether certain references should have been disclosed. Put another way, if it turned out that there were other memos or communications related to the prosecution of the '018 Patent which stated that such references should be disclosed to the PTO, those memos or communications would have to be produced. Included within this would be drafts of Dr. Jones's chart or memo which might have contained a different conclusion, memos of others who questioned Dr. Jones's conclusion, and the like.

The Court found that the Order did not encompass the entirety of all things which Regeneron had an obligation to disclose to the PTO generally, nor did it extend to Regeneron's analysis of draft claim language. It also did not necessarily extend as far as requiring all consideration of all disclosures for other patents, even in the same family. The Court required Regeneron to confirm to Merus that it had produced or would produce:

> 1. All documents from anyone involved directly or indirectly in prosecuting the '018 Patent, relating to whether prior art should be or should have been disclosed as part of the prosecution of the '018 Patent . . . .
> 2. To avoid any doubt, the following documents are included within the scope of the above directive:
>
> a. All documents of any kind from the files of Dr. Jones and others with whom he worked on the prosecution of the '018 Patent regarding whether or not to disclose prior art to the PTO. All documents of any kind from the files of anyone else who was involved (directly or indirectly) in the prosecution of the '018 Patent and who may not be captured in paragraph 1 above, who gave consideration to the relevance or applicability of prior art to the '018 Patent.

(ECF No. 272, at 6-7 (emphasis added).) Regeneron confirmed it had produced what was required.

A bench trial on Merus's claim of inequitable conduct was scheduled to commence on June 8, 2015. On May 29, 2015, and in compliance with this Court's rules which require a party's witnesses to testify by declaration/affidavit on direct (subject to live cross-examination and redirect), Regeneron submitted trial affidavits from Drs. Smeland and Jones, both attorneys acting as attorneys. At this time, Regeneron's privilege log indicated that it had withheld many documents from Dr. Smeland's files, which he had authored or received on the basis of the attorney/client privilege and/or work product doctrine. The same was true with regard to Dr. Jones except as to those which Regeneron had earlier produced following the motion practice described above.

Merus cried foul and argued that Regeneron was again engaging in a sword/shield use of the attorney client privilege and moved to strike these affidavits based on, inter alia, the assertion that Regeneron had shielded privileged

documents from disclosure that were now directly implicated by the trial declarations. According to Merus, the Jones Trial Affidavit relied heavily on information that Regeneron failed to disclose during fact discovery and in response to the Court's prior waiver order. In particular, Merus cited Dr. Jones's deposition testimony that apart from a phone call that he had made to the PTO to schedule a meeting, he could not recall a single other communication with the Examiner during the '018 Patent prosecution. Late-produced billing records were now referenced in Dr. Jones's trial affidavit.

The issue was, if anything, far worse with regard to Dr. Smeland. With regard to Dr. Smeland, Merus argued that he was now proposing to testify as to his views regarding the meaning of claim language and broadly regarding his subjective understanding of the meaning of various aspects of the Withheld References, when Regeneron had withheld from its production numerous documents on those topics on the basis of privilege.

The Court reviewed each of the trial affidavits. The Court agreed that a comparison of these affidavits with entries on Regeneron's privilege logs raised a number of concerns. In his affidavit, Dr. Smeland made dozens of assertions regarding his understanding of the scope of the invention in the '176 application, his state of mind, and what he knew and thought about each of the Withheld References at the time of patent prosecution continuing up to "today." The Courts in Regeneron I and Regeneron II provided lengthy lists of these assertions, which

implicated Dr. Smeland's knowledge and state of mind directly—both during patent prosecution and throughout litigation.

He used these statements to counter Merus's assertion that he acted in bad faith by discussing what he knew, believed, understood, communicated, etc. There is certainly a good tactical reason to confront Merus's position with testimony from Dr. Smeland. However, that tactical choice must occur in the context of other choices made throughout the litigation—choices as to whether to waive attorney-client privilege or not. Here, Regeneron made a litigation choice to maintain the attorney-client privilege as to Dr. Smeland's work with regard to prosecution of the '176 application and his knowledge and thoughts regarding the Withheld References generally over time and specifically with regard to the prosecution of the '176 application. In maintaining its assertion of privilege on these topics, Regeneron used the protections of the Federal Rules of Civil Procedure to shield Dr. Smeland's documents relating to those topics from disclosure.

This was a choice that was within Regeneron's discretion—but not a choice that allows them to have it both ways at trial. By making the choice to maintain the privilege and withhold the documents, Regeneron chose the tactical path of not delving into state of mind or knowledge to defend against the claim of inequitable conduct. And of course, given the heavy burden that a proponent of an inequitable conduct bears of proving materiality and intent by clear and convincing evidence, this was not an unreasonable choice. As with any affirmative disclosure of

information otherwise protected by the attorney-client privilege, once the disclosure of the affidavit was made, as it was not inadvertent, the waiver was complete.

Thus, on the day that Regeneron disclosed Dr. Smeland's trial affidavit, it waived the privilege as to the subject matter of each of the topics the affidavit addressed. This was intentional and permanent. As described above, this included his views on meaning and scope of claim language, understanding of the technology, materiality (including cumulativeness) of each of the Withheld References. Many of his documents are to or from Dr. Murphy, while others involve Dr. Jones. And as noted below, this process revealed a host of withheld non-privileged documents. Accordingly, the waiver rippled throughout the case.

The problem, of course, was how this position at trial interacted with Regeneron's discovery obligations. In order to take this position at trial, Regeneron was obligated to have previously produced the documents from Dr. Smeland's files that would have allowed Merus to test his various assertions. This would have substantially altered a significant swath of discovery, including Dr. Smeland's deposition, the deposition of others with whom he interacted, expert discovery, and on. Regeneron did not fulfill its discovery obligations in this regard. That is clear both from a review of the log and the Court's in camera review of documents on the log. There are dozens of documents on Regeneron's privilege log which are from Dr. Smeland's files, and which concern these very topics.

The Court conducted an in camera review of the documents on the log. Regeneron was, after all, asserting it had done all it was obligated to do. Merus

pointed to seemingly inconsistent entries on the log. As it turned out, the log was "Pandora's Box." The Court's review revealed that Merus was certainly correct—there were dozens of "Smeland documents" as to which the privilege had now been waived.

But the in camera review revealed far more. It revealed additional serious discovery issues: a number of non-privileged documents related to topics at issue throughout the litigation had been withheld on the basis of privilege, and other documents that should have been produced pursuant to the order regarding the Jones Memo issue had not in fact been disclosed. In all, there were three categories of documents that presented serious concerns of discovery misconduct:

1. Non-privileged documents that were not produced and instead have resided throughout this case on the privilege log (e.g., numerous Excel spreadsheets with scientific test results, third party filings to the PTO, fact statements by non-lawyers not seeking legal advice, etc.).
2. Previously privileged documents as to which Regeneron affirmatively waived the privilege and that this Court ordered be produced pursuant to its February 25, 2015 order. (ECF No. 272.)
3. Documents on the privilege log relating to precisely those topics waived by Regeneron on May 29, 2015 when it filed its trial declarations.

The Court determined that failure to make full and adequate production of documents in the first two categories during the period of fact discovery itself and independently of the trial misconduct warranted serious sanction. The production

failure is undoubtedly larger than the few exemplars revealed by the Court's own review. Given the many thousands of documents on Regeneron's privilege log, the Court could not know the full extent of the problem.

As to the first category, there were spreadsheets related to scientific tests, published articles, correspondence with third parties—all of which were relevant to issues in the case. The ultimate importance of the documents in this category is unclear, but that Merus should have had them long ago is not.

In the second category, there are a number of documents on the log which Dr. Jones is on discussing communication with the PTO, before and after the meeting on March 2013. These should have been produced as part of the "Jones Memo" waiver issue.

The third category of documents presents its own very serious issues. Many documents on the log are directly relevant to the topics as to which privilege has been waived. Some of those documents contain statements directly contradictory to Smeland's sworn trial declaration.

To allow into evidence at trial declarations from witnesses to whom these three categories of documents relate could only have occurred—in fairness—if there was a wholesale re-opening of discovery. As a first step, a top-to-bottom re-review of the Regeneron privilege log would have been necessary. This would have to have been followed by additional document production, fact depositions, and revised expert reports and depositions. Given the Court's concerns with Regeneron's process, the Court would have required that any such process only occur with the

direct oversight of a special master. It is clear that this process and the attendant discovery would have consumed substantial time and cost. It would also undoubtedly have required further judicial resources. This would not have been a fair burden for Merus or this Court.

The Court considered whether striking the trial affidavits and precluding Smeland and Murphy from testifying at trial would be a sufficient remedy and decided it would not. Simply striking those two declarations and precluding trial testimony from just them would not sufficiently address the many issues that had come into play; those issues spread broadly into the case.

First, the first two categories of documents themselves revealed a separate need for a re-review of the privilege log, production, and of course depositions as needed. Second, striking the declarations and precluding certain witnesses alone would have failed to remedy the substantial disruption and delay that would be caused by Regeneron's conduct. Third, merely striking the declarations and precluding certain witnesses would have failed to recognize Regeneron's pattern of conduct throughout this litigation. That conduct included, inter alia, a host of issues at the outset regarding infringement contentions, positions in relation to claim construction and positions and representations with regard to the Court's February 25 Order (the Jones Memo Order). The Court also understood that Regeneron's trial counsel was not responsible for the preparation of the privilege log and was not counsel at the outset of this case when the first issue occurred (though they were counsel for the Jones Memo Order). In all events, this pattern by

Regeneron was just that—a pattern. Merely striking the declarations and precluding testimony would have treated the most recent issues as isolated and remediable—when they were yet another step in a long pattern of litigation choices that have caused delay, inefficient use of resources, and diversion from the merits.

The Court carefully considered the appropriate combination of remedies that would best—and most narrowly—have addressed where the parties and the Court found themselves in litigation just before trial was set to commence. The Court included in its analysis of appropriate remedy the history of conduct that Regeneron has engaged in to this point. Under these highly unusual circumstances, the Court precluded the testimony of Smeland, Murphy, and Jones. In recognition of the implications the discovery conduct has on the entirety of the case, the Court also found that it was appropriate to impose the sanction of an adverse inference as to the intent of Smeland and Murphy with regard to inequitable conduct during patent prosecution. See Residential Funding Corp. v. DeGeorge Fin. Corp., 306 F.3d 99, 108-10 (2d Cir. 2002). The Court therefore inferred that Drs. Smeland and Murphy together knew of each of the Withheld References, knew they were material, and made a deliberate decision to withhold them. In short, they acted with the specific intent to deceive the patent office. The Court found that this is "the single most reasonable inference able to be drawn from the evidence." Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011) (quoting Star Sci., Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008)); see also Residential Funding, 306 F.3d at 108 (discussing circumstances in which "[t]he

sanction of an adverse inference may be appropriate"). The Court therefore found by clear and convincing evidence that Drs. Smeland and Murphy knew of the Withheld References, knew of their materiality, and made the deliberate decision to withhold them.

C. The Appeal

The District Court was affirmed by the Federal Circuit, with two judges affirming and one judge dissenting. Regeneron II, 864 F.3d 1343. The majority opinion agreed with this Court's finding as to the broadest reasonable construction of the patent claims at issue and held that this Court did not clearly err in finding that the Withheld References were but-for material. Id. at 1352-53, 1356. As to this Court's imposition of sanctions, the majority found that the Court did not abuse its discretion, as "Regeneron's behavior in district court was beset with troubling misconduct." Id. at 1356. The majority additionally noted that Regeneron did not, on appeal, "meaningfully dispute any of the factual findings underlying the district court's decision." Id.

In dissent, Judge Newman did not dispute this Court's factual findings as to Regeneron's misconduct during litigation. Rather, she focused on the fact that "the district court inferred intent to deceive during prosecution and invalidated the patent, as a sanction for purported attorney misconduct during this litigation." Id. at 1365 (Newman, J., dissenting). She also disagreed with this Court's determination that the Withheld References were but-for material. Id. at 1367.

On December 26, 2017, the Federal Circuit denied Regeneron's petition for panel rehearing and rehearing en banc. Regeneron Pharm., Inc. v. Merus, N.V., 878 F.3d 1041 (Fed. Cir. 2017). On January 11, 2018, Merus requested to renew its motion for attorney fees, which this Court had stayed pending resolution of the appeal. (See ECF Nos. 425, 431, 449.) The Court allowed Regeneron to respond but ultimately lifted the stay on the motion on January 18, 2018. (ECF No. 455.)

II. LEGAL PRINCIPLES

In "exceptional cases," a district court "may award reasonable attorney fees to the prevailing party" pursuant to the Patent Act. 35 U.S.C. § 285. An "exceptional case" is one that "stands out from others with respect to the substantive strength of a party's litigating position . . . or the unreasonable manner in which the case was litigated." Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S. Ct. 1749, 1756 (2014); see also Highmark Inc. v. Allcare Health Mgmt. Sys., Inc., 134 S. Ct. 1744, 1748 (2014) (noting that "the word 'exceptional' in § 285 should be interpreted in accordance with its ordinary meaning" (citing Octane Fitness, 134 S. Ct. at 1755).

The determination of whether a case is exceptional is made by looking at the "totality of the circumstances." Octane Fitness, 134 S. Ct. at 1756. Either "inequitable conduct before the P.T.O." or "misconduct during litigation" can "form a basis for finding a case exceptional." Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989); see also Gaymar Indus., Inc. v. Cincinatti Sub-Zero Prods., Inc., 790 F.3d 1369, 1372 (Fed. Cir. 2015) ("To be sure, the conduct of the parties is a relevant factor under Octane's totality-of-the-circumstances

inquiry . . . ."); Kilopass Tech., Inc. v. Sidense Corp., 738 F.3d 1302, 1308 (Fed. Cir. 2013) (noting that "[a] case may be deemed exceptional when there has been some material inappropriate conduct related to the matter in litigation, such as . . . inequitable conduct in procuring the patent, misconduct during litigation, vexatious or unjustified litigation, conduct that violates [Federal Rule of Civil Procedure] 11, or like infractions" (citation omitted) (alteration in original)); Therasense, 649 F.3d at 1289 (noting that "prevailing on a claim of inequitable conduct often makes a case 'exceptional,' leading potentially to an award of attorneys' fees under 35 U.S.C. § 285").

For example, an "overall vexatious litigation strategy and numerous instances of litigation misconduct are sufficient to support an exceptional case determination." Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd., 726 F.3d 1359, 1367 (Fed. Cir. 2013). In another case, a court held that a finding of inequitable conduct during litigation was supported by, inter alia, a party's incorrect responses to interrogatories (which were never formally corrected) and production of documents near the end of trial that had been requested earlier. Nilssen v. Osram Sylvania, Inc., 528 F.3d 1352, 1359 (Fed. Cir. 2008).

Whether a case is exceptional "is a factual determination." Forcillo v. Lemond Fitness, Inc., 168 Fed. App'x 429, 430 (Fed. Cir. 2006). This inquiry is discretionary and does not require clear and convincing evidence; rather, it is "governed by a preponderance of the evidence standard," Octane Fitness, 134 S. Ct. at 1758; see also Gaymar Indus., 790 F.3d at 1372 ("We review the district court's

factual findings underlying an exceptional case determination for clear error. And we review the district court's determination of whether a case is "exceptional" for an abuse of discretion." (internal citation omitted)); Stephens v. Tech Int'l, Inc., 393 F.3d 1269, 1273 (Fed. Cir. 2004) (noting that whether a case is "exceptional" is a factual finding made by the district court).

Separately, while the Patent Act does not include a provision for the award of expert fees or costs, the Court may award these as sanctions. See MarcTec, LLC v. Johnson & Johnson, 664 F.3d 907, 921 (Fed. Cir. 2012) ("A district court has inherent authority 'to impose sanctions in the form of reasonable expert fees in excess of what is provided for by statute.'" (quoting Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc., 549 F.3d 1381, 1391 (Fed. Cir. 2008)). However, "not every case that qualifies as exceptional under § 285 will also qualify for sanctions under the court's inherent power." Id. A finding of "fraud or abuse of the judicial process" is required before the Court will award expert fees and/or costs. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., No. 95-cv-8833, 2002 WL 1733681, at *1 (S.D.N.Y. July 26, 2002) (citing Amsted Indus., Inc. v. Buckeye Steel Castings Co., 23 F.3d 374, 378 (Fed. Cir. 1994)).

III. DISCUSSION

At issue here is the type of "exceptional case" in which one party conducted litigation in an unreasonable manner. While the finding of inequitable conduct alone warrants an award of attorney fees to Merus, the Court need not rely on that ground, as Regeneron's conduct during litigation is surely enough.

Throughout litigation, Regeneron, inter alia: (1) failed to abide by this Court's Individual Rules, even after being instructed to do so; (2) failed to produce discovery and withheld evidence; (3) misrepresented facts to the Court and to Merus; and (4) used privilege as a sword and a shield. As to the third item, Regeneron specifically withheld: (1) non-privileged documents; (2) previously privileged documents as to which Regeneron affirmatively waived the privilege and which this Court ordered be produced pursuant to its February 25, 2015 Order; and (3) documents on the privilege log relating to precisely those topics waived by Regeneron on May 29, 2015 when it filed its trial declarations.

This misconduct began soon after the case was filed and continued until the Court finally conducted an in camera review of Regeneron's privilege log on the eve of trial. Only then, when it was too late to reopen discovery, did the Court discover the massive amount of information withheld from it (and from Merus) over the preceding year. Indeed, the extent of Regeneron's mischief was so vast that the Court noted it could not delay trial and require production of the documents to Merus without appointing a special master to oversee Regeneron's production—to do so would likely be futile. Regeneron I, 144 F. Supp. 3d at 595.

Regeneron claims that the fact of Judge Newman's dissents in Regeneron II and in the Federal Circuit's denial of Regeneron's petition for rehearing en banc, in which Judge Reyna joined, demonstrate that "the case was not . . . 'objectively unreasonable.'" (ECF No. 466, Regeneron's Response in Opp. to Merus's Mot. for Attorneys' Fees, Experts' Fees, and Costs ("Mem. Opp.") at 8.) It relies on a

Southern District of New York case that held a Federal Circuit judge's dissent indicated that the movant's litigation position was not "objectively baseless." Bayer Schera Pharma AG v. Sandoz, Inc., No. 08-cv-3710, ECF No. 208 (S.D.N.Y. Aug. 27, 2012). Accordingly, that court denied a post-appeal motion for attorneys' fees.

However, Regeneron's reliance on this case is misplaced for two reasons. First, this opinion, written in 2012, relied on the pre-Octane Fitness standard, which required clear and convincing evidence that the lawsuit was "objectively baseless." Id. at 8-9. But as the parties are aware, in 2014, the Supreme Court held in Octane Fitness that the "inquiry is discretionary and does not require clear and convincing evidence; rather, it is 'governed by a preponderance of the evidence standard.'" 134 S. Ct. at 1758. While a Federal Circuit judge's dissent may indicate that a movant cannot meet the "clear and convincing" standard, it is not dispositive under a "preponderance of the evidence" standard.

Additionally, however, Bayer is inapposite because here, the Court is focused on Regeneron's litigation tactics. Judge Newman's Regeneron II dissent did not take issue with this Court's factual findings as to Regeneron's litigation tactics and award of sanctions. Judge Newman argued that this Court erred by holding "the '018 patent unenforceable on grounds of inequitable conduct as a sanction for Regeneron's 'litigation misconduct' relating to discovery and the privilege log during this litigation." Regeneron II, 864 F.3d at 1365. She did not, however, argue that the litigation misconduct did not occur.

In deciding a motion for attorney fees, a district court need only determine whether the case is exceptional, as described above. Severe litigation misconduct, such as that which occurred here, supports a finding that the case is exceptional—there is no need to rely on the finding of inequitable conduct. Judge Newman's argument that the Court erred in other respects does not undermine this determination.

Regeneron also argues that this Court has twice already sanctioned Regeneron for its litigation tactics and need not do so again by awarding attorney fees to Merus. But an award of fees address a different issue than a merits decision; a fee award acknowledges the financial costs Merus had to bear in defending itself. Regeneron I, 144 F. Supp. 3d 530.

Further, in an attempt to reduce the fees awarded to Merus, Regeneron claims that one month after this Court's claim construction opinion in November 2014, Regeneron moved to dismiss Merus's unenforceability counterclaim without prejudice, "which would have absolved Merus of any infringement liability for the claims in this case and rendered Regeneron's claims invalid." (Mem. Opp. at 11.) By continuing to litigate, Regeneron contends, Merus incurred additional fees for which Regeneron should not be responsible. However, once this litigation had commenced, Merus was under the taint of a patent infringement claim. It was not obligated to continue conducting business under that taint. It had the right to finish what Regeneron had started; that is, to continue to litigate until it was

publicly absolved of any and all liability. The attorney fees it therefore incurred in connection with the appeal are thus not excluded from this award.

Finally, Regeneron argues that Merus should not be awarded expert fees, as Regeneron's use of experts was not improper. However, Regeneron's misconduct surely supports the award of expert fees and costs as sanctions, especially as Regeneron's failure to produce evidence likely drove up Merus's expert fees and costs. (See ECF No. 467, Merus' Reply Br. in Supp. of Its Mot. for Attorneys' Fees, Expert Fees and Costs ("Reply Br.") at 10, n.4.)

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Merus's motion for attorney fees, expert fees, and costs. As Merus has not yet submitted a detailed explanation of those costs, the Court will not at this time take up the issue of the amount of such award. The parties are ordered to confer on a schedule for submission of those records and Regeneron's opposition, if any will be filed. The parties shall file a letter to the Court outlining that schedule **not later than fourteen days from the issuance of this Opinion**.

SO ORDERED.

Dated: New York, New York
March 26, 2018

KATHERINE B. FORREST
United States District Judge